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09/626,326	07/26/2000	William G. Hubbard	047542/0197	8619

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FOLEY & LARDNER  
321 NORTH CLARK STREET  
SUITE 2800  
CHICAGO, IL 60610-4764

EXAMINER

STRZELECKA, TERESA E

ART UNIT PAPER NUMBER

1637

DATE MAILED: 02/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/626,326

Applicant(s)

HUBBARD ET AL.

Examiner

Teresa E Strzelecka

Art Unit

1637

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 14 October 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-41 and 57-64 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9, 12-15, 19-29, 32-35, 39-41 and 57-64 is/are rejected.
- 7) ☒ Claim(s) 10, 11, 16-18, 30, 31 and 36-38 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

### DETAILED ACTION

1. This office action is in response to an amendment filed October 14, 2003. Claims 1-73 were pending. Applicants cancelled claims 42-56 and 65-73. Claims 1-41 and 57-64 are pending and will be examined. Applicants omitted pending claim 41 from the listed claims. However, for the sake of advancing the prosecution, claim 41 will be considered as well. The claim is reiterated below:

41. (Amended) In a biocompatible composition for augmenting tissue, the biocompatible composition comprising a biomaterial for augmenting a desired tissue site and a biocompatible, resorbable, lubricous carrier for the biomaterial, the improvement comprising a polysaccharide gel carrier, having a viscosity between about 20,000 centipoise to about 350,000 centipoise, the carrier maintaining the biomaterial homogeneously suspended in the biocompatible composition prior to augmentation of a desired tissue site and during introduction of the biocompatible composition to the desired site.

2. Applicants' claim cancellations and arguments overcame the following rejections: rejection of claims 14-18, 34-38 and 50-54 under 35 U.S.C. 112, second paragraph; rejection of claims 42-44, 48-56 and 65-73 under 35 U.S.C. 102(e) over Chu et al.; rejection of claims 45-47 under 35 U.S.C. 103(a) over Chu et al. and Hubbard.

3. This office action is made non-final because of new grounds for rejection.

#### *Claim interpretation*

4. For the purpose of art rejections, the limitation of the polysaccharide gel viscosity in claims 1 and 21 is interpreted in the following way:

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A) for carboxymethylcellulose gels, examples of which are provided by Applicants on pages 27, 36, 38, 43-49, any carboxymethylcellulose gel with weight % concentration between 0.25 and 5% will be considered as possessing viscosity in the range of 20,000 to 350,000 centipoise;

B) for all the other polysaccharides, for which examples of concentration ranges and viscosities have not been provided, any concentration of the polysaccharide will be considered as fulfilling the viscosity requirement.

Properties of the polysaccharide gel such as “biocompatible”, “resorbable” and “lubricous” are inherent properties of the polysaccharide gels, therefore a prior art disclosing polysaccharide gels anticipates a claim to such gels being biocompatible, resorbable and lubricous. In addition, properties of ceramic particles such as “biocompatible”, “non-resorbable” and “finely divided” are inherent properties of spherical ceramic particles, therefore a prior art disclosing spherical ceramic particles anticipates a claim to such particles being biocompatible, non-resorbable and finely divided (see MPEP 2112.01).

#### **2112.01 Composition, Product, and Apparatus Claims**

**PRODUCT AND APPARATUS CLAIMS — WHEN THE STRUCTURE RECITED IN THE REFERENCE IS SUBSTANTIALLY IDENTICAL TO THAT OF THE CLAIMS, CLAIMED PROPERTIES OR FUNCTIONS ARE PRESUMED TO BE INHERENT**

Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). “When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not.” In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the prima facie case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. In re Best, 562 F.2d at 1255, 195 USPQ at 433. See also Titanium Metals Corp. v. Banner, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985) (Claims were

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directed to a titanium alloy containing 0.2-0.4% Mo and 0.6-0.9% Ni having corrosion resistance. A Russian article disclosed a titanium alloy containing 0.25% Mo and 0.75% Ni but was silent as to corrosion resistance. The Federal Circuit held that the claim was anticipated because the percentages of Mo and Ni were squarely within the claimed ranges. The court went on to say that it was immaterial what properties the alloys had or who discovered the properties because the composition is the same and thus must necessarily exhibit the properties.).

See also *In re Ludtke*, 441 F.2d 660, 169 USPQ 563 (CCPA 1971) (Claim 1 was directed to a parachute canopy having concentric circumferential panels radially separated from each other by radially extending tie lines. The panels were separated "such that the critical velocity of each successively larger panel will be less than the critical velocity of the previous panel, whereby said parachute will sequentially open and thus gradually decelerate." The court found that the claim was anticipated by Menget. Menget taught a parachute having three circumferential panels separated by tie lines. The court upheld the rejection finding that applicant had failed to show that Menget did not possess the functional characteristics of the claims.); *Northam Warren Corp. v. D. F. Newfield Co.*, 7 F. Supp. 773, 22 USPQ 313 (E.D.N.Y. 1934) (A patent to a pencil for cleaning fingernails was held invalid because a pencil of the same structure for writing was found in the prior art.).

5. Limitations of claims 1 and 21 pertaining to maintaining the homogeneous suspension of biomaterial and limitations of claims 19, 20, 39 and 40 are intended use limitations, which do not provide any structural constraints on the product of claims 1 and 21 in terms of comparison of the product with compositions described in the prior art.
6. The term "biomaterial" has not been defined, therefore it will be interpreted as any material.

***Claim Rejections - 35 USC § 102***

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 1-5, 7, 8, 19-28, 39, 40, 41 and 57-64 are rejected under 35 U.S.C. 102(b) as being anticipated by Hisatsuka et al. (RE 31,664).

Claims 19, 20, 39 and 40 are considered together with claims 1 and 21, since they do not contain any additional structural limitations for the compositions of claims 1 and 21.

Regarding claims 1, 19, 20, 21, 39, 40 and 41, Hisatsuka et al. teach polysaccharide gels formed from the following polysaccharides: polysaccharide obtained from a soil microorganism (col. 4, lines 10-27; col. 5, lines 8-67; Table 1; Fig. 3, 4, 10), with viscosity in the range of 0 to about  $10^5$  centipoise (cp) for the concentration range of 0 to about 1% (Fig. 10); agar, gels with concentration ranging from 0.5 to 2% (Table 1; Fig. 3, 4); sodium alginate, gels with viscosity in the range of 0 to about  $10^5$  centipoise (cp) for the concentration range of 0 to about 3% (Fig. 10); xanthan gum, gels with viscosity in the range of 0 to about  $5 \times 10^4$  centipoise (cp) for the concentration range of 0 to about 3% (Fig. 10); sodium cellulose sulfate, gels with viscosity in the range of  $5 \times 10^2$  centipoise to about  $5 \times 10^3$  centipoise (cp) for the concentration range of 1 to about 3% (Fig. 10); carrageenan, gels with viscosity in the range of 0 to about  $10^3$  centipoise (cp) for the concentration range of 0 to about 1% (Fig. 10).

Regarding claims 2 and 22, Hisatsuka et al. teach aqueous polysaccharide gels (col. 5, lines 14-30).

Regarding claims 3 and 23, Hisatsuka et al. teach a polysaccharide obtained from soil microorganism (col. 13, lines 15-38; Fig. 3, 4, 10), agar, sodium alginate, xanthan gum, sodium cellulose sulfate and carrageenan (Fig. 3, 4, 10).

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Regarding claims 4, 5, 24 and 25, Hisatsuka et al. teach sodium cellulose sulfate (Fig. 10).

Regarding claims 7 and 27, Hisatsuka et al. teach polysaccharide gel comprising water (col. 5, lines 14-30).

Regarding claims 8 and 28, Hisatsuka et al. teach polysaccharide gel comprising aqueous solutions of methanol, ethanol and isopropanol (col. 6, lines 7-20; Table 2).

Regarding claims 57 and 61, Hisatsuka et al. teach additives such as buffers, NaCl (col. 5, lines 14-30) and alcohols (col. 6, lines 7-20).

Regarding claims 58 and 62, Hisatsuka et al. teach additives such as buffers (col. 5, lines 14-30).

Regarding claims 59, 60, 63 and 64, Hisatsuka et al. teach polysaccharide gels with viscosities from 0 to about  $10^5$  cp (Fig. 10). Since Applicants did not provide guidance regarding concentrations of all possible polysaccharides which would result in viscosities in the range of 150,000 to 250,000 cp, the gels of Hisatsuka et al. anticipate these claims.

9. Claims 1-7, 12, 13, 19-28, 32, 33, 39, 40, 41 and 57-64 are rejected under 35 U.S.C. 102(e) as being anticipated by Ammann et al. (U.S. Patent 5,158,934).

Claims 19, 20, 39 and 40 are considered together with claims 1 and 21, since they do not contain any additional structural limitations for the compositions of claims 1 and 21.

Regarding claims 1, 19, 20, 21, 39, 40 and 41, Ammann et al. teach polysaccharide gels formed from polysaccharides constituting 1.9% by weight of the gel (col. 10, lines 55-62), and gels containing 2-5% methylcellulose (col. 11, lines 43-47). Therefore, even though Ammann et al. do not specifically teach gel viscosities in the range of 20,000 to 350,000 centipoise, since Applicants did not provide guidance regarding concentrations of all possible polysaccharides which would

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result in viscosities in the range of 20,000 to 350,000 cp, the gels of Ammann et al. anticipate these claims.

Regarding claims 2 and 22, Ammann et al. teach aqueous polysaccharide gels (col. 12, lines 35-38).

Regarding claims 3 and 23, Ammann et al. teach cellulose polysaccharides, starch, agar, alginates, agarose, carrageenan, xanthan gum, oligosaccharides, etc. (col. 10, lines 67, 68; col. 11, lines 1-12).

Regarding claims 4, 5, 24 and 25, Ammann et al. teach cellulose polysaccharides, such as methylcellulose, carboxymethylcellulose, hydroxypropyl methylcellulose, etc. (col. 10, lines 67, 68; col. 11, lines 1-5).

Regarding claims 6 and 26, Ammann et al. do not specifically teach sodium carboxymethylcellulose, but they do teach carboxymethylcellulose and derivatives thereof (col. 11, lines 1-12), therefore they teach sodium carboxymethylcellulose as well.

Regarding claims 7 and 27, Ammann et al. teach polysaccharide gel comprising water (col. 12, lines 35-38).

Regarding claims 12 and 32, Ammann et al. teach biomaterials comprising titanium alloy or ceramic block (col. 8, lines 49-67; col. 9, lines 1-5).

Regarding claims 13 and 33, Ammann et al. teach biomaterials comprising ceramic blocks (col. 8, lines 49-67; col. 9, lines 1-5).

Regarding claims 57 and 61, Ammann et al. teach additives such as buffers and rhTGF- $\beta$ 1 (col. 12, lines 34-40).

Regarding claims 58 and 62, Ammann et al. teach additives such as sodium acetate buffer (col. 12, lines 34-40).



Regarding claims 59, 60, 63 and 64, Ammann et al. teach polysaccharide gels formed from polysaccharides constituting 1.9% by weight of the gel (col. 10, lines 55-62), and gels containing 2-5% methylcellulose (col. 11, lines 43-47). Therefore, even though Ammann et al. do not specifically teach gel viscosities in the range of 150,000 to 250,000 centipoise, since Applicants did not provide guidance regarding concentrations of all possible polysaccharides which would result in viscosities in the range of 150,000 to 250,000 cp, the gels of Ammann et al. anticipate these claims.

10. Claims 1, 12-15, 21 and 32-35 are rejected under 35 U.S.C. 102(e) as being anticipated by Staley et al. (U.S. Patent 5,503,771).

Regarding claims 1 and 21, Staley et al. teach suspensions of colloidal particles (= biomaterial) in polysaccharide gels, such as alginate, agar or agarose (col. 4, lines 20-31 and 39-50; col. 6, lines 1-6 and 61-67; col. 7, lines 1-10; col. 12, lines 50-65; col. 13, lines 46-48 and 59-67). Therefore, even though Staley et al. do not specifically teach gel viscosities in the range of 20,000 to 350,000 centipoise, since Applicants did not provide guidance regarding concentrations of all possible polysaccharides which would result in viscosities in the range of 20,000 to 350,000 cp, the gels of Staley et al. anticipate these claims.

Regarding claims 12 and 32, Staley et al. teach biomaterials comprising colloidal metal or ceramic particles (col. 4, lines 20-23).

Regarding claims 13 and 33, Staley et al. teach biomaterials comprising ceramic particles (col. 4, lines 20-23).

Regarding claims 14 and 34, Staley et al. teach biomaterials comprising ceramic particles (col. 4, lines 20-23).

Regarding claims 15 and 35, Staley et al. teach ceramics such as alumina (col. 4, lines 57-59).

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11. Claims 1, 2, 9, 21, 22 and 29 are rejected under 35 U.S.C. 102(b) as being anticipated by Chibata et al. (U.S. Patent 4,138,292).

Regarding claims 1 and 21, Chibata et al. teach carriers for suspension of enzymes or microorganisms (= biomaterial), the carriers comprising polysaccharide gels, where the polysaccharides are carrageenan, furcellaran or cellulose sulfate (col. 2, lines 6-11 and 50-55). Therefore, even though Chibata et al. do not specifically teach gel viscosities in the range of 20,000 to 350,000 centipoise, since Applicants did not provide guidance regarding concentrations of all possible polysaccharides which would result in viscosities in the range of 20,000 to 350,000 cp, the gels of Chibata et al. anticipate these claims.

Regarding claims 2 and 22, Chibata et al. teach aqueous polysaccharide gels (col. 2, lines 41-44).

Regarding claims 9 and 29, Chibata et al. teach the gel further comprising glycerin (col. 5, lines 58-62; col. 6, line 45).

#### ***Allowable Subject Matter***

12. Claims 10, 11, 16-18, 30, 31 and 36-38 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

#### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Teresa E Strzelecka whose telephone number is (571) 272-0789. The examiner can normally be reached on M-F (8:30-5:30).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

TS  
January 29, 2003

  
JEFFREY FREDMAN  
PRIMARY EXAMINER